



## ENVIRONMENTAL PROTECTION AGENCY

**[FRL-9845-1; EPA-HQ-ORD-2009-0229, ORD-2013-0111, ORD-2013-0430]**

**Announcement of the IRIS Public Meeting Schedule for Calendar Years 2013 and 2014;  
Announcement of the Availability of Preliminary Materials for *tert*-Butyl Alcohol, Ethyl  
*tert*-Butyl Ether, and Hexahydro-1,3,5-trinitro-1,3,5-triazine; and Announcement of a  
Public Meeting on these Preliminary Materials**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of a series of public meetings and the availability of preliminary materials.

**SUMMARY:** EPA's Integrated Risk Information System (IRIS) Program is committed to proactive stakeholder engagement, increased transparency, and using the best available science in IRIS assessments. In accordance with the recently announced enhancements of the IRIS Program, EPA is announcing a series of public meetings for calendar years 2013 and 2014 to obtain public input at specific stages in the process of developing an IRIS assessment.

EPA is also announcing the availability of preliminary materials for three chemicals, *tert*-butyl alcohol (*tert*-butanol), ethyl-*tert*-butyl ether (ETBE), and hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX), which will be discussed at the first public meeting scheduled for October 23-24,

2013. The preliminary materials for *tert*-butanol and ETBE are posted on the IRIS website, and the preliminary materials for RDX will be posted approximately 60 days before the meeting. These materials are being released for public viewing and comment prior to the public meeting on October 23-24, 2013, which will provide an opportunity for the IRIS Program to engage in early discussions (before the IRIS assessments have been prepared) with stakeholders and the public on data that may be used to identify health hazards and characterize exposure-response relationships.

**DATES:** The 2013 and 2014 IRIS public meetings will be held on the dates specified below. They will begin at 10:00 a.m. and end at 5:00 p.m., Eastern Time, or earlier, if comments and discussions have been completed. For planning purposes, a 2-day time period has been reserved for the meetings, but the actual duration will be specified when the topics are identified for each meeting. The meeting dates are set, but topics will be specified in the draft agendas provided for each meeting throughout the year. All future announcements and information about the meetings planned for 2013 and 2014, and the availability of preliminary materials for any chemicals undergoing review by the IRIS Program, will be posted on the IRIS website (<http://www.epa.gov/iris/publicmeetings/>). Meeting information will be posted well in advance (generally 60 days) of each meeting; no further announcements for the 2013 and 2014 public meetings or the availability of preliminary materials will be made in the Federal Register. In the event there are no materials to be presented or discussed for any of the set meeting dates, a notice canceling the meeting will be posted on the IRIS website.

**Meeting Date**

**Topics**

October 23-24, 2013

*tert*-Butyl alcohol (*tert*-Butanol)  
Ethyl *tert*-butyl ether (ETBE)

## Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)

The following meeting dates are set. Topics will be specified well in advance of each meeting.

December 12-13, 2013

February 26-27, 2014

April 23-24, 2014

June 25-26, 2014

September 3-4, 2014

October 29-30, 2014

December 15-16, 2014

### **ADDRESSES:**

The public meetings announced in this notice will be held at an EPA conference room at One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, Virginia, 22202. To gain entrance to this EPA building, attendees must register at the security desk in the lobby and present photo identification. A webinar and teleconference line will also be available for registered attendees/speakers. Broad public participation will ensure that EPA uses the best available science in risk assessment. For those who are unable to attend in person, EPA encourages participation via the webinar or teleconference line.

*Information on Services for Individuals with Disabilities:* EPA welcomes public attendance at the IRIS public meetings and will make every effort to accommodate persons with disabilities. For information on access or services for individuals with disabilities, contact Christine Ross, IRIS Staff, Environmental Protection Agency, National Center for Environmental Assessment, Mail Code: 8601P; telephone: 703-347-8592; facsimile: 703-347-8689; or e-mail: [ross.christine@epa.gov](mailto:ross.christine@epa.gov) (reference the October 23-24, 2013 IRIS public meeting) and include your name and contact information.

## **FOR FURTHER INFORMATION CONTACT:**

For general information about IRIS public meetings, please contact Christine Ross, IRIS Staff, Environmental Protection Agency, National Center for Environmental Assessment (NCEA), Mail Code: 8601P; telephone: 703-347-8592; facsimile: 703-347-8689; or e-mail: [ross.christine@epa.gov](mailto:ross.christine@epa.gov). For information regarding the subject matter of a specific meeting, please contact the EPA representative identified on the IRIS public meeting website (<http://www.epa.gov/iris/publicmeeting/>).

## **SUPPLEMENTARY INFORMATION:**

### **I. Information about IRIS**

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. The IRIS database contains information for more than 500 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the human health risk assessment process. When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health.

## II. IRIS Public Meetings

Public meetings will be held approximately every 2 months beginning on October 23-24, 2013. Materials for the public meetings will be posted on the IRIS website (<http://www.epa.gov/iris/publicmeetings/>) well in advance of the meeting (generally 60 days). The meetings will provide an opportunity for the public to provide input on preliminary materials prior to development of the draft assessment and provide input on drafts of assessments and charges to the peer review panels prior to external peer review. The planned meeting dates for calendar years 2013 and 2014 are: October 23-24, 2013; December 12-13, 2013; February 26-27, 2014; April 23-24, 2014; June 25-26, 2014; September 3-4, 2014; October 29-30, 2014; and December 15-16, 2014.

In step 1 of the IRIS process (development of the draft assessment), EPA will release preliminary materials comprised of draft literature search strategies describing the processes for identifying and screening scientific literature and the literature search results, and preliminary evidence tables and preliminary exposure-response arrays summarizing key characteristics and findings from critical studies that EPA proposes to consider in identifying hazards and characterizing exposure-response relationships. EPA will hold a public meeting to discuss these materials. In step 4 of the IRIS process (public review and comment/independent expert peer review), EPA will release the draft assessment and draft peer review charge for public comment and also hold a public meeting to discuss these materials.

The draft literature search strategies, preliminary evidence tables, and preliminary exposure-response arrays are responsive to the National Research Council (NRC) 2011 report *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*, in

which the NRC recommended ways to improve the development of IRIS assessments. The literature search strategies, which describe the processes for identifying scientific literature, screening studies for consideration, and selecting studies to include in evidence tables, are responsive to NRC recommendations regarding systematic review of the scientific literature. The preliminary evidence tables and preliminary exposure-response arrays are responsive to the NRC recommendation for presenting key study data in a standardized manner.

EPA welcomes all comments on the draft literature search strategies, preliminary evidence tables, and preliminary exposure-response arrays, including comments on:

- the clarity and transparency of the materials;
- the approach for identifying pertinent literature;
- the selection of studies for data extraction to preliminary evidence tables and exposure-response arrays;
- methodological considerations that could affect the interpretation of or confidence in study results; and
- additional studies published or nearing publication that may provide data for the evaluation of human health hazard or exposure-response relationships.

The IRIS Program believes that public involvement can be most beneficial at the early stages of developing an assessment. Releasing the draft literature search strategy, preliminary evidence tables, and exposure response arrays early will ensure that critical research is not omitted and communicates to the public why critical studies were chosen for further evaluation, helping frame major scientific issues and ultimately leading to more efficient production of assessments. In order to promote such early public involvement and increase transparency, EPA will in many

cases be releasing materials that reflect preliminary deliberations that are subject to further evolution as the assessment continues. Consequently, meeting materials provided at the early stage of an assessment, such as preliminary evidence tables, have not been subjected to external peer review, and they do not constitute EPA policy, nor represent any Agency determination. Such materials are being distributed with the sole objective of facilitating a public meeting that is intended to promote the use of the best available science and improve the utility and clarity of IRIS assessments.

### **III. Meeting Registration and Presentations**

Registrants will be required to provide their name, title, affiliation, sponsor (if different from affiliation), and contact information. If you intend to request time on the agenda to make a specific presentation, please register no later than 30 days before the meeting to attend in person or via webinar/teleconference. All other participants should register no later than 7 days before the meeting. Participants that want to make a specific presentation should indicate such in their registration and provide the length of time required. In general, presentations should be no more than 30 minutes. Please submit any written materials to the appropriate docket number for the subject chemical, as specified in **Section III** of this notice, no later than 7 days before the meeting. If there are more requests for presentations than time allows, the time limit for each presentation will be adjusted. During the meeting, remote attendees and individuals attending the meeting in person are welcome to make comments, ask questions, and participate in the dialogue. Details regarding registration procedures (in person, via webinar, or teleconference) will be posted on the IRIS website (<http://www.epa.gov/iris/publicmeeting/>).

#### **IV. Meeting Materials and Public Involvement**

Materials for the public meetings will be posted well in advance (generally 60 days) of each meeting on the IRIS website (<http://www.epa.gov/iris/publicmeeting/>). A limited number of paper copies will be available from the Information Management Team, NCEA; telephone: 703-347-8561; facsimile: 703-347-8691. If you request a paper copy, please provide your name, mailing address, and the title of the document you are requesting.

#### **V. October 23-24, 2013, Public Meeting on *tert*-Butanol, ETBE and RDX**

The October 23-24, 2013 public meeting will be devoted to discussing the preliminary materials for *tert*-butanol, ETBE, and RDX. The preliminary materials for *tert*-butanol and ETBE are posted on the IRIS website (<http://www.epa.gov/iris/publicmeeting/>), and the preliminary materials for RDX will be posted approximately 60 days before the meeting on or about August 23, 2013. The *tert*-butanol materials will be discussed first, followed by ETBE and RDX. EPA may add additional chemicals to the agenda if materials become available in time to allow adequate notice to the public. If additional chemicals are added to the October 23-24, 2013 meeting agenda, they will be posted on the IRIS website approximately 60 days before the meeting on or about August 23, 2013. A more detailed agenda for the meeting will be posted on the IRIS website shortly after speaker registration closes.

The preliminary evidence tables and preliminary exposure-response arrays should be regarded solely as representing the data on each endpoint that have been identified as a result of the draft literature search strategy. They do not reflect any conclusions about hazard identification or dose-response assessment. After obtaining public input and conducting



additional study evaluation and data integration, EPA will revise these materials to support hazard identification and dose-response assessment in the draft Toxicological Reviews for *tert*-butanol, ETBE, and RDX.

For the October 23-24, 2013 meeting, if you intend to request time on the agenda to make a specific presentation, please register no later than September 23, 2013. All other participants should register no later than October 16, 2013. Please submit any written materials (including scheduled presentation materials) to the appropriate docket number specified in **Section III** of this notice no later than October 16, 2013. If there are more requests for presentations than time allows, the time limit for each presentation will be adjusted. Details regarding registration procedures (in person, via webinar, or teleconference) will be posted on the IRIS website.

**VI. How to Submit Materials to the Docket at <http://www.regulations.gov>**

*General Instructions:* EPA invites the public to submit comments and other relevant information regarding the chemicals discussed at a public meeting to the appropriate docket number established for each chemical. Such data, information, or comments may be submitted to the appropriate docket identified by the Docket ID number by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting materials.
- E-mail: [Docket\\_ORD@epa.gov](mailto:Docket_ORD@epa.gov).
- Facsimile: 202-566-9744.
- Mail: Office of Environmental Information (OEI) Docket (Mail Code: 28221T),  
U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW,

Washington, DC 20460. The telephone number is 202-566-1752. If you provide materials by mail, please submit one unbound original with pages numbered consecutively, and three copies of the materials. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

- Hand Delivery: The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

*Instructions:* Direct your *tert*-butanol materials to Docket ID No. EPA-HQ-ORD-2013-0111, ETBE materials to EPA-HQ-ORD-2009-0229, and RDX materials to EPA-HQ-ORD-2013-0430. Please submit your materials as early as possible. It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at <http://www.regulations.gov>, including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other

information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an “anonymous access” system, which means that EPA will not know your identity or contact information unless you provide it in the body of your materials. If you send e-mail comments directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD-ROM you submit. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your materials. Electronic files should avoid the use of special characters and any form of encryption and be free of any defects or viruses. For additional information about EPA’s public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

*Instructions for Submitting Information to the tert-Butanol Docket:* The October 23-24, 2013 public meeting announced in this Federal Register will discuss *tert*-butanol. The docket number for *tert*-butanol is EPA-HQ-ORD-2013-0111. Persons submitting relevant information

on *tert*-butanol should follow the general instructions provided above using the *tert*-butanol docket number.

*Instructions for Submitting Information to the ETBE Docket:* The October 23-24, 2013 public meeting announced in this Federal Register will discuss ETBE. The docket number for ETBE is EPA-HQ-ORD-2009-0229. Persons submitting relevant information on ETBE should follow the general instructions provided above using the ETBE docket number.

*Instructions for Submitting Information to the RDX Docket:* The October 23-24, 2013 public meeting announced in this Federal Register will discuss RDX. The docket number for RDX is EPA-HQ-ORD-2013-0430. Persons submitting relevant information on RDX should follow the general instructions provided above using the RDX docket number.

Dated: August 2, 2013.

Lynn Flowers,  
Acting Director, National Center for  
Environmental Assessment.

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